MedSun Reporting by Biomedical and Clinical Engineers – Safety Stories and Successes

Medical Product Safety Network

MedSun Webinar
July 24, 2012
Charles McCullough, MSEE

MedSun

800-859-9821

medsun@fda.hhs.gov

Learning Objectives

- Increase your awareness and understanding of FDA's MedSun program
- Learn about the unique contribution of Biomedical and Clinical Engineering staff to FDA's understanding of device safety issues in the field
- Increase your awareness of the types of device-related information that FDA likes to see in MedSun reports
- Learn about two hospitals' experiences and their efforts to resolve device problems

What is MedSun?

- What does it have to do with the Safe Medical Device Act (SMDA)?
- Is it “MedWatch on steroids?” (Quoting a biomedical engineer)
- Is it FDA sponsored – or something else?
- What do you want us to report?
- How does reporting fit into the hospital’s safety program?
- Where do Biomedical and Clinical Engineers and technicians fit into MedSun?

MedSun – What it is:

- A project of FDA's Center for Devices and Radiological Health (CDRH) that has been in existence since 2002
- A network of 300 hospitals nationwide
- Hospitals can meet their reporting requirements through participation in MedSun – but it's more about Voluntary Reporting and creating a triangle of communication

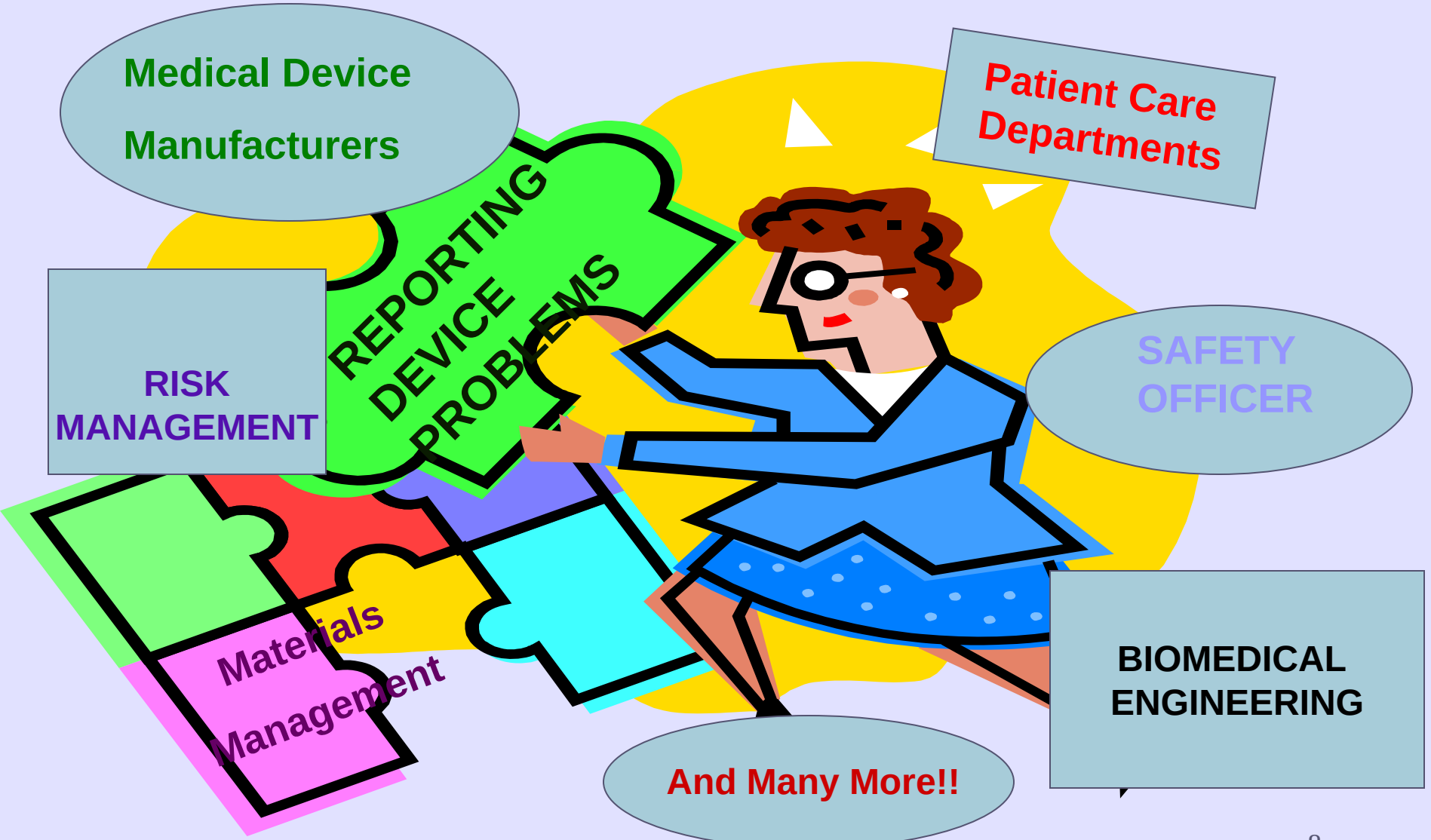
MedSun - You have FDA's ear:

- The FDA (CDRH) regulates medical device manufacturers
- We need the perspective of medical device users about safety concerns, issues, and near misses.
- Your hospital also benefits when you report "potential for harm" issues and concerns
- From the Biomed's Mouth to the FDA's Ears | August 2009 | 24x7
- "*Device Failure? Here's What FDA Wants to Know*"; AAMI Tech World, September 2010

Types of Medical Devices and Examples

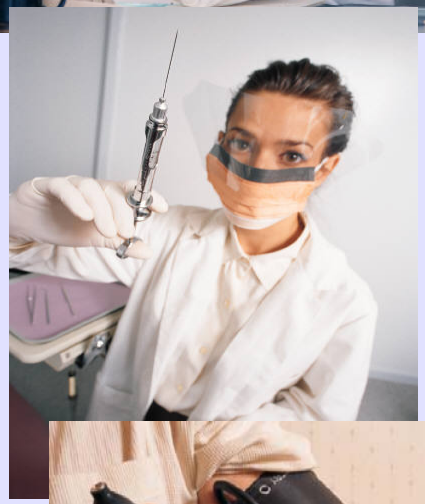
- **Capital Equipment**
  - cribs, beds, scales, wheelchairs, IV poles, infusion pumps, bathing tubs, blood pressure equipment, MRI and CAT scanners, radiology equipment
- **Instruments**
  - surgical staplers, glucose meters, orthopedic tools and hardware
- **Monitoring Systems**
  - cardiac, telemetry, vital sign monitors, pulse oximeters
- **Clinical Lab**
  - Reagents
  - Chemistry analyzers
- **Disposables & Accessories**
  - ventilator breathing circuits, filters
  - needles, syringes, trocars, IV catheters, IV tubing, foley catheters, feeding tubes, gloves
  - electrodes
- **Implantable**
  - defibrillators, breast implants, ventriculoperitoneal shunts,, tissue expanders, pacemakers
- **Computerized Medical Systems**
  - Workstations, hardware
  - software

All Departments are an Important Piece of the Patient Safety Puzzle ! (the Manufacturer, too)



What Kinds of Things Should You Report?

- Problems you haven't seen before
- An increase in well-known problems
  - Instructions / labeling
  - Defects
  - Software problems
  - Failure to work as intended / malfunction
  - Interactions with other devices
  - Human factors
  - Unsafe designs
  - Problems encountered with off-label use
  - Other problems that might result in harm (fatigue; staffing; unfamiliar equipment)



Biomedical / Clinical Engineers and technicians:

- Are in a unique role, with hands-on technical knowledge of many medical devices and systems
- Work closely with users when they have problems with equipment
- Are often in communication with manufacturers about problems and solutions
- Can provide valuable insight about the design of equipment they service
- Often observe “use error” scenarios that can be related to poor human factors design.

When Do I Report?

- When you think a device has or may have caused or contributed to any of the following outcomes (for a patient, staff member or visitor):
  - Death
  - Serious injury
  - Minor injury
  - Close calls, potential for harm*, safety concerns

Biomedical Engineering Repairs versus MedSun Reports

"Repairs are what we do, but what should I report?"

What do you think FDA needs to know to improve the safety of the medical devices you deal with?

BiomedTalk Listserv

- “Has anyone else seen this problem?...”
- “Someone should tell FDA about this...”
- “The manufacturer is telling us they are working on a fix...”

What Do We Mean by "Potential* for Harm"?

- **Events that are caught before anything harmful occurred**
  - OR table dropped suddenly but staff able to "catch" patient
- **Important observations of a chronic problem with a device**
  - IV pump frequently requires repair of cassette doors
- **Problems which lead staff to develop "work-arounds"**
  - End-users frequently apply tape to secure an easily dislodged component or control
- **"Out-of-the-box" problems that are identified before use on a patient**
  - A high percentage of new infusion pumps fail Biomedical incoming performance inspection
- **Human Factors issues**
  - A PCA pump with programming so complicated and "un-intuitive" that even biomedical engineers (and the company's salesman) could easily mis-program it

* Be sure to explain the potential safety implication!

Typical device safety concerns that Clinical/Biomedical Engineers become aware of

- **Battery issues** – short life, ineffective charging, premature failure
- **Interoperability issues** – problems with compatibility and communication between interconnected (including networked) devices
- **Medical Device Integration** – issues which stem from the evolving world of medical device integration with EHRs and other Health IT products
- **Design issues** – designs seem prone to failure, mechanically unsound or difficult to use and/or maintain
- **Software issues** – lockups, reboots, error messages, need to reload or upgrade software
- **Manufacturer "fixes"** – parts kits, upgrades, notifications
- **Interference and RFI/EMI issues**

Details to report…

- **If there was an injury, what happened to the persons affected?**
  - "...loss of ventilation, patient was manually ventilated..."
- **What, specifically, were the problems with the device(s) involved?**
  - "..ventilator displayed "Error 130" message and stopped ventilating.."
- **What, if any, were the original medical procedures for which the devices were used?**
- **What, if any, were the follow-up medical procedures required because of the event?**
  - repeat surgery, antibiotics administered
- **What are the names of the manufacturers of the devices involved?**
- **What are the relevant manufacturer device identification numbers?**
  - serial, model, lot, catalog, and any other specific information
- **What did you do to solve the problem?**

SAVE THE DEVICE, ACCESSORIES AND PACKAGING!

Additional information that Clinical/Biomedical Engineers can supply

- Copies of manufacturer and/or biomedical service reports
- Information on any additional testing done to determine the cause of the problem
- Photos illustrating the specific problem
- Information from the Biomedical Engineering Computerized Maintenance Management Software (CMMS - maintenance software) database:
  - Includes device identifiers, service history, age of equipment, trends
  - MedSun is working with some cooperating sites to explore “data-mining” of CMMS data to identify potential device safety signals
- Your technical expertise in explaining the nature of the problem and the safety implications

Biomedical Engineering and ways you can help:

- Get to know and work with the Risk Management / Safety staff who report adverse events and concerns to MedSun
- They can use your engineering and technical knowledge for help in understanding and explaining even “non-biomed” devices
- Share your concerns about common device problems, frequent use error scenarios and knowledge of recalls of which you become aware

Why Reporting Medical Device Problems Is Important In Your Hospital

- Prevent future problems and protect patients, staff, families, and visitors
- Contribute to hospital quality management goals
- Collaborate with manufacturers and the FDA
- Outcomes can include recalls and corrective actions such as manufacturing or labeling changes
- Impact the public health for the nation's patients and health care providers

Robyn Frick, CCE
Biomedical Engineer
Eastern Maine Medical Center

Eastern Maine Medical Center℠
Inspiring confidence in care

Cancer Care of Maine

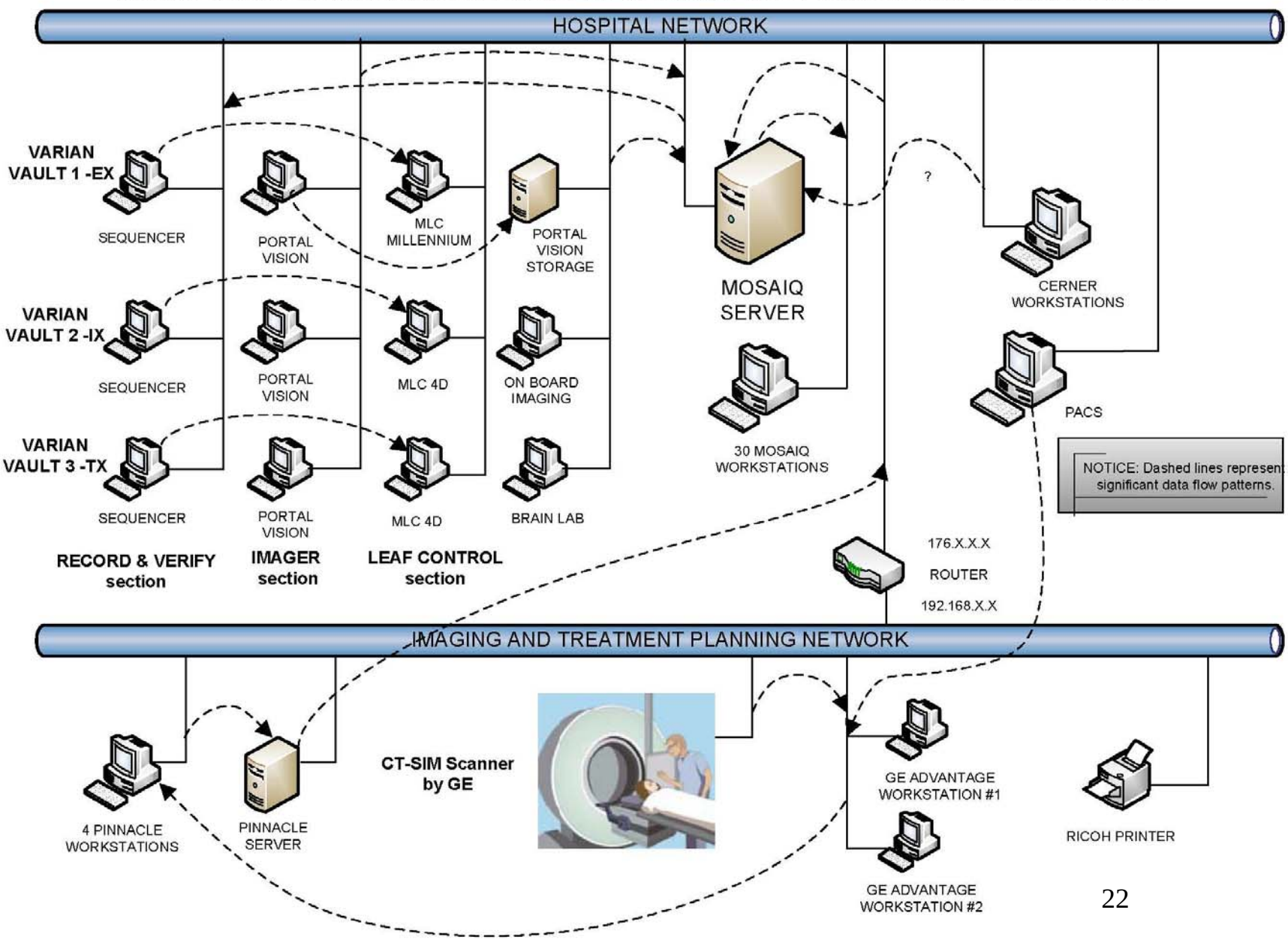
60,000 sf, $41 mil outpatient cancer hospital, offering state of the art Medical and Radiation Oncology

Opened December 2009

Robyn W. Frick, CCE
Biomedical Engineer
Eastern Maine Medical Center
489 State Street PO Box 404
Bangor, ME 04402-0404
Phone: 207-973-7698

TOGETHER We're Stronger

EMHS MEMBER


MULTIPLE SYSTEMS MANAGEMENT FOR CCOM RADIATION ONCOLOGY Denis Santerre & Robyn Frick 10-22-2010
HOSPITAL NETWORK
VARIAN VAULT 1 -EX
SEQUENCER
PORTAL VISION
MLC MILLENNIUM
PORTAL VISION STORAGE
VARIAN VAULT 2 -IX
SEQUENCER
PORTAL VISION
MLC 4D
ON BOARD IMAGING
VARIAN VAULT 3 -TX
SEQUENCER
PORTAL VISION
MLC 4D
BRAIN LAB
RECORD & VERIFY section
IMAGER section
LEAF CONTROL section
MOSAIQ SERVER
30 MOSAIQ WORKSTATIONS
?
CERNER WORKSTATIONS
PACS
NOTICE: Dashed lines represent significant data flow patterns.
176.X.X.X
ROUTER
192.168.X.X
IMAGING AND TREATMENT PLANNING NETWORK
4 PINNACLE WORKSTATIONS
PINNACLE SERVER
CT-SIM Scanner by GE
GE ADVANTAGE WORKSTATION #1
GE ADVANTAGE WORKSTATION #2
RICOH PRINTER

Varian LINAC UPS utilized a Breaker Panel supplied to them by a third party (GEXPRO)

- PROBLEM: GEXPRO breaker panel. 2 each 12V-4Ah Batteries are used to hold in the breaker for “safety stop” switches and for testing.
- Battery chargers were inferior and caused battery overheating and failure. Breakers began tripping prematurely.
- Varian initially told us that GEXPRO supports the chargers – not them…

Eastern Maine Medical Center℠
Inspiring confidence in care

TOGETHER We're Stronger
EMHS MEMBER

After the report was filed through MedSun…

- Varian began working with GEXPRO to identify an acceptable solution
- GEXPRO came up with an upgrade kit, and Varian let us know how to obtain and install it.
- It was installed by in-house electrician
- Varian now takes us seriously on all requests for help on their third party items.

Eastern Maine Medical Center℠
Inspiring confidence in care

David Stiles, CBET

Director of Biomedical Engineering & Central Equipment Services

Long Beach Memorial Medical Center and Millers Children's Hospital

Long Beach Memorial Medical Center
Miller Children's Hospital

750+ Bed Medical Center
Heart Institute
Women's Hospital
Regional Trauma Center

David Stiles, CBET
Director
Department of Biomedical Engineering & Central Equipment Services
dstiles@memorialcare.org
562.933.0573

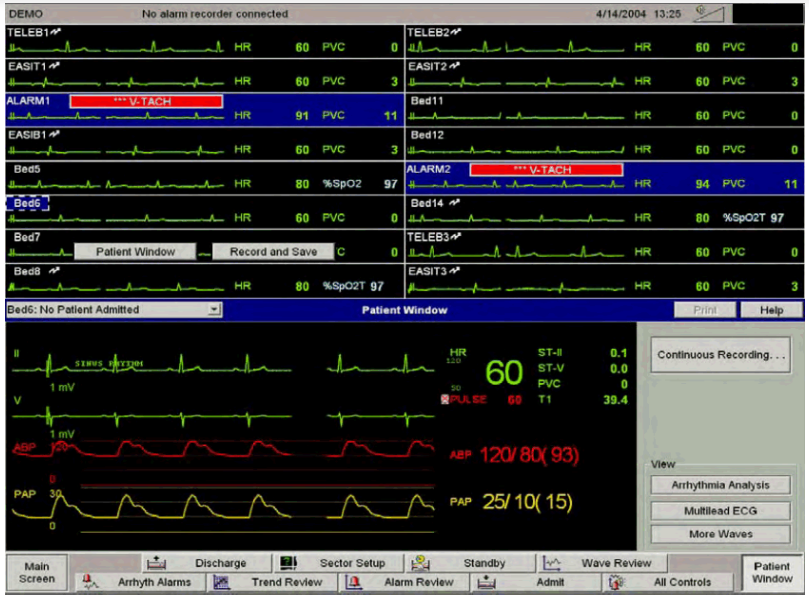
- Accountability
- Best practices
- Compassion
- Synergy

MEMORIALCARE® HEALTH SYSTEM
Excellence in Health Care

Physiological Monitor Lockup

MemorialCare Health System
Excellence in Health Care

- Event occurred in our 56 bed telemetry monitoring station under the watch of an ECG monitoring technician.
- While transferring control of the mouse and keyboard to another set of displays via a keyboard, video, and mouse switch (KVM), the technician lost control of the mouse and keyboard operation.
- The technician was unable to:
  - Select bed sectors
  - Silence alarms
  - Use touch screens
  - Enter patient data
- Recycling the KVM switch did not return the central monitor back to normal operation.
- Biomedical technician responded and had to reboot affected central station CPU.



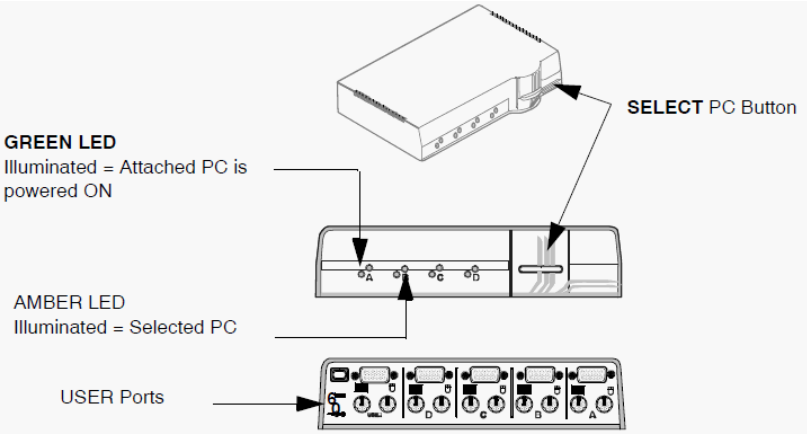
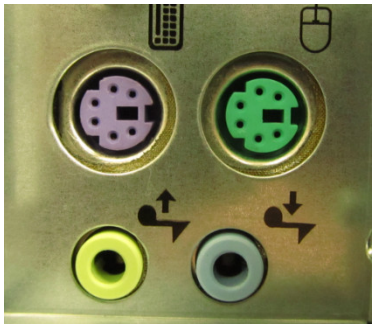


Figure 2-15 Keyboard-Video-Mouse Switch

Determining Event Cause



Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of This Report (mm/dd/yyyy)
5/14/2012	5/15/2012

5. Describe Event or Problem

Title: Central Station Lock-Up
Event Desc: During telemetry monitoring the ECG monitoring technician noted that the mouse and keyboard were unresponsive when trying to access one of the telemetry central stations. Biomedical technician found that the touch screen on the display was non-responsive. Central station was re-booted and display touch, keyboard, and mouse returned to proper functioning. Biomedical determined that touch screen failure also cause keyboard and mouse to lock. Biomedical scheduled follow up with manufacturer of central station.

What was the original intended procedure?
Patient monitoring.
Device Usage Problem: Device failed (e.g. broke, couldn't get it to work or stopped wo

6. Relevant Tests/Laboratory Data, Including Dates

Performance Test on 5/15/2012: Prior to reboot, biomed was able to operate the second central station when transferring on the keyboard/mouse switch to display #1. When returned back to display #2, the keyboard and mouse became

PLEASE TYPE OR USE BLACK INK

#1	#1	8. Event Reappeared After Reintroduction?
#2	#2	#1 ☐ Yes ☐ No ☐ Doesn't Apply
9. NDC# or Unique ID		#2 ☐ Yes ☐ No ☐ Doesn't Apply

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name	IntelliVue	
2. Common Device Name	Monitor, Physiological, Central System	
3. Manufacturer Name, City and State	Manufacturer contact information is on page 3	
4. Model # M3150	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☐ Lay User/Patient ☒ Other:
Serial # 2UAQ150RRRR	Other #	
6. If Implanted, Give Date (mm/dd/yyyy)	7. If Explanted, Give Date (mm/dd/yyyy)	

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☒ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

- Biomedical determined lockup was due to the KVM switchovers by monitoring technician. Failure was duplicated after several test attempts.
- Biomedical also noted keyboard mouse failures when disconnected and re-inserted into KVM switch or directly into central CPU.
- Biomedical determined that central CPU exhibited similar PS2 interface failures that occurred on Windows PC based operating systems using PS2 connections.
- Equipment manufacturer followed up by adding a DC power supply to the KVM switch to remove “spurious voltages” during KVM switch activations.
- MedSun report submitted.

Post MedSun Report

MemorialCare Health System
Excellence in Health Care

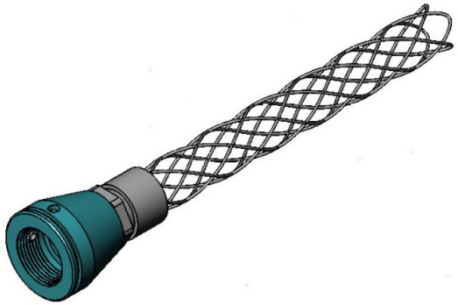
- Biomedical report listed on MAUDE database.
- Equipment manufacturer followed up by adding a DC power supply to the KVM switch to remove “spurious voltages” during KVM switch activations.
- Biomedical discovered additional interface issues including:
  - Use of unsecured and weak connections: S-Video, HDMI, and low voltage power connections that easily slip loose

- Many disconnections go unnoticed by end user until device or feature failure.
- Biomedical has surveyed and provided connection securement and strain relief.
- Mobile equipment especially susceptible to connection failure.
- We suspect these same failures occur elsewhere at other hospitals.

Why We Report to MedSun

MemorialCare Health System
Excellence in Health Care

- Many equipment related adverse events occur from weak or failed electrical connections.
- Unexpected failures can and do occur from common component design.
- We report to point these out to the medical community and to the manufacturer to determine repeat failures at other facilities.
- We seek to have the manufacturers improve their designs in the interest of patient safety.



Patient Safety has many pieces… YOU are *the expert piece*… MedSun can't do it without you!

Just…Please Report

Contact Us!

800-859-9821

medsun@fda.hhs.gov

Public Website:

www.fda.gov/medsun

Thank you!